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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,049	01/18/2006	David M. Hammerbeck	C1271.70077US00	1834

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WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,049	HAMMERBECK ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11,12,15-21,35-37,39,41,43 and 45* is/are pending in the application.

4a) Of the above claim(s) *36,37,41,43 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12,15-21 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 5/10/2010. Claims 1, 4-7 and 35 are amended. Ne claim 49 is added. Claims 1-7, 11, 12, 15-21, 35-37, 39, 41, 43 and 45 and 49 are pending. Claims 36, 37, 41, 43 and 45 are withdrawn form consideration.

2. Previous objection that are not reiterated herein are withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 15-21 and 35 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Skwierczynski et al. (US 6,245,776) for reasons of record and with a statement to note that recitation of "for delivery of an immune response modifier to the nasal passage of a subject" is an intended use and route of administration of the composition.

5. Skwierczynski discloses composition comprising immune response modifier and carrier components (abstract; column 14, lines 7, 15, 24, 44, 58-67; column 15, lines 1-44). Immune response modifier listed in columns 3-13 meets the immune response modifier of claims 1, 2, 11, 12, 15-21 and 35. Example 1 contains xanthan gum that meets the limitation of claims 1 and 3-7. The xanthan gum in Example 1, Table 1 is present at 0.5%, which is at least 0.1%.

6. The recitation in the currently amended claim 1 that the composition is "for delivery of an immune response modifier to the nasal passage of a subject" is an intended use and route of administration of the composition.

7. Xanthan gum is a specific polysaccharide having carboxylic acid group so that new claim 49 is anticipated.

8. Therefore, Skwierczynski anticipates the designated claims.

Response to Arguments

9. Applicant's arguments filed 5/10/2010 have been fully considered but they are not persuasive.

10. Applicant argues that Skwierczynski, the 6,245,776 patent does not teach that the composition comprising the immune response modifier is administered to the nasal passage.

11. Response: The recitation that the "formulation is for delivery of an immune response modifier to the nasal passage of a subject" is an intended use of the formulation at the intended route of administration. Therefore, Skwierczynski properly anticipated the claimed formulation.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-7, 15-21 and 35 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crooks et al (US 6,331,539) or Miller et al. (US 6,083,505) in view of Skwierczynski et al (US 6,245,776) for reasons of record with a modification to address the amendment.

15. Crooks: Crooks discloses pharmaceutical composition that comprises the immune response modifier of claims 1, 2, 11, 12, 15-21 and 35 and carrier components (abstract, column 2, lines 8-14; column 14, lines 26-45 and claims 26-28).

16. Crooks does not teach the pharmaceutical carriers of claims 1 and 3-7.

17. The recitation that the "formulation is for delivery of an immune response modifier to the nasal passage of a subject" is an intended use of the formulation at the intended route of administration.

18. However, immune response modifiers of the types disclosed by Crooks have been formulated with xanthan gum at 0.5% (see the whole document of Skwierczynski with emphasis on abstract; column 14, lines 7, 15, 24, 44, 58-67; column 15, lines 1-44).

19. The xanthan gum is a specific polysaccharide having carboxylic acid group so that limitation of new claim 49 is anticipated.

20. Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the immune response modifier of Crooks can be formulated with xanthan gum because the immune response modifier have been successfully formulated with xanthan gum according to Skwierczynski.

21. Miller: Miller discloses pharmaceutical composition comprising immune response modifier of claims 1, 2, 11, 12, 15-21 and 35 and carriers (see column 3, lines 4-11; column 8, lines 61-67; claims 1 and 12).

22. Miller does not teach the pharmaceutical carriers of claims 1 and 3-7.

23. However, immune response modifiers of the types disclosed by Miller have been formulated with xanthan gum at 0.5% (see the whole document of Skwierczynski with emphasis on abstract; column 14, lines 7, 15, 24, 44, 58-67; column 15, lines 1-44).

24. The xanthan gum is a specific polysaccharide having carboxylic acid group so that limitation of new claim 49 is anticipated.

25. Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the immune response modifier of Miller can be formulated with xanthan gum because the immune response modifier have been successfully formulated with xanthan gum according to Skwierczynski.

Response to Arguments

26. Applicant's arguments filed 5/10/2010 have been fully considered but they are not persuasive.

27. Applicant argues that none of the references teach or suggest delivery of the claimed composition to the nasal passage.

28. Response: The examiner claim is not to method of use of a composition where the method involves administration or delivery of the composition to the nasal passage. Rather, the claims are directed to compositions and the recitation that the "formulation is for delivery of an immune response modifier to the nasal passage of a subject" is an intended use of the formulation at the intended route of administration. The rejection is maintained.

29. No claim is allowed.

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

31. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618